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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,144

03/25/2004

Robert Costa

03-284-E

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20306

7590

01/08/2009

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EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

01/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/809,144	<b>Applicant(s)</b> COSTA ET AL.	
	<b>Examiner</b> Mark Halvorson	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 9/23/2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50 and 54-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50 and 54-65 is/are allowed.
- 6) ☒ Claim(s) 66-71 is/are rejected.
- 7) ☒ Claim(s) 72 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/23/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

Claims 50 and 54-72 are pending and under examination.

### NEW REJECTIONS: Based on the Amendment

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherr et al (US Patent No. 5,723,313, issued March 3, 1998, previously cited).

The claims are drawn to a method for inhibiting proliferation of a tumor cell in vitro comprising the step of inhibiting FoxM1B activity in the tumor cell by contacting the cell with a p19ARF fragment in vitro, wherein the p19ARF fragment has the amino acid sequence as set forth in SEQ ID NO:10, wherein FoxM1B activity is inhibited by causing Fox1B to localize in the nucleolus of the tumor cell, wherein Fox1B activity is inhibited by preventing Fox1B nuclear localization, wherein the tumor cell is a malignant tumor cell, wherein the tumor cell is of epithelial origin, wherein the epithelial cell is skin epithelial cell. The open claim language of claim 66 is interpreted as encompassing p19ARF fragments which include SEQ ID NO:10 up to the full length p19ARF protein. Thus claims 66-71 are drawn to a genus of p19ARF fragments.

Sherr et al claims a method of preventing abnormal cell growth in a mammalian cell comprising administer a composition comprising a pharmaceutically acceptable carrier and an effective amount of a peptide, wherein said peptide consists of 10 to 50 amino acid residues comprising the amino acid sequences of SEQ ID NO:47 (ARG ARG PHE LEU VAL THR), and SEQ ID NO:48 (ARG ARG PRO ARG). The amino acid

sequence of SEQ ID NO:48 (Arg, Arg, Pro Arg) is an amino acid sequence of SEQ ID NO:10. Thus, the genus of p19ARF fragments encompassed by claim 17 of Sherr et al would overlap with the genus of p19ARF fragments of claims 66-71. While Sherr et al do not explicitly disclose that the ARF-p19 inhibits FoxM1B activity by preventing FoxM1B nuclear localization and causing FoxM1B polypeptide to localize to the cytoplasm, some Sherr et al's ARF-p19 peptides would inherently possess the ability to prevent FoxM1B nuclear localization and cause FoxM1B polypeptide to localize to the cytoplasm because these are functions carried out by the ARF-p19 polypeptide, as evidenced by Kalinichenko et al (see page 841, columns 1 and 2, Genes Devel 18:830-850, 2005). Sherr et al also discloses that the preferred cancer cell is a melanoma cells. (column 6, lines 36-39).

### ***Conclusion***

Claims 50 and 54-65 are allowed.

Claims 66-71 stand rejected

Claim 72 is objected to as being dependent on a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson  
Patent Examiner  
571-272-6539

/MISOOK YU/  
Primary Examiner, Art Unit 1642